

K121034

p. 1/2

3. 510(k) Summary

PREPARED: September 3, 2012 **SEP 4 2012**

510(k) SPONSOR: ICONACY Orthopedic Implants, LLC
PO Box 1033
Warsaw, IN 46581-1033
or
4130 Corridor Drive
Warsaw, IN 46582

CONTACT PERSON: Roy Y Hori, PhD
Executive Vice President, R&D
(574)269-4622 or (574)306-2450
rhor@iconacy.com

TRADE NAME: ICONACY™ I-Hip™ System

COMMON NAMES: Total Hip System

CLASSIFICATION, and CLASS: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR Section 888.3358, Class II)
Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis (21 CFR Section 888.3360, Class II)

PRODUCT CODES: LPH, LWJ

PREDICATE DEVICES: Taperloc Femoral Components (K043537)(K921301)(K110400), Regenerex Ringloc + Modular Acetabular Shell (K070369), ArComXL Polyethylene Liners (K042051)

DEVICE DESCRIPTION: The ICONACY I-Hip consists of a collarless, tapered, forged titanium alloy femoral stem, mated to a cobalt chrome modular femoral head. This femoral construct articulates with an acetabular device assembly. The acetabular device assembly consists of a hemispheric titanium alloy cup (i.e., shell) coupled with a highly cross linked ultra-high molecular weight polyethylene (HXL-UHMWPE) liner. Forty percent of the femoral stem is circumferentially coated with a titanium coating designed to attain a cementless, press fit fixation. The acetabular cup is machined from forged Ti-6Al-4V ELI alloy. The cup has a threaded polar hole for insertion and two screw holes to permit the use of screws for adjunct fixation. The outer hemispheric surface of the cup has a titanium plasma spray coating for cementless, press fit fixation. A titanium locking ring is fixed into a groove on the cup to engage the groove in the HXL-UHMWPE liner. Standard instrumentation is used to implant the device.

K121034

p.2/2

INDICATIONS FOR USE: The ICONACY I-Hip system is indicated for the following conditions: (1) a severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia, (2) avascular necrosis of the femoral head, (3) acute traumatic fracture of the femoral head or neck, (4) failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement, (5) certain cases of ankylosis, (6) nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The ICONACY I-Hip system consists of femoral stem and acetabular cup (i.e., shell) porous coated components intended for cementless, press-fit fixation

BASIS FOR SUBSTANTIAL EQUIVALENCE: The ICONACY I-Hip is substantially equivalent to the Taperloc and Ringloc devices in design, materials, function and indications for use.

Performance Data: Nonclinical testing was conducted to demonstrate substantial equivalency to the predicate devices including characterization of the HXL-UHMWPE, testing of the locking mechanism between the cup and liner, range of motion analysis, impingement testing, wear, femoral head pull off testing, and fatigue (endurance limits) for the femoral stem.

Clinical Testing: Clinical testing was not required for determining substantial equivalency with the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

ICONACY Orthopedic Implants, LLC
% Roy Y. Hori, Ph.D.
Executive Vice President, R&D
4130 Corridor Drive
Warsaw, Indiana 46582

SEP 4 2012

Re: K121034

Trade/Device Name: ICONACY™ I-Hip™ System

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH, LWJ

Dated: August 23, 2012

Received: August 27, 2012

Dear Dr. Hori:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K121034

Device Name: ICONACY™ I-Hip™ System

Indications for Use:

The ICONACY I-Hip system is indicated for the following conditions:

1. A severely painful and/or disabled hip joint as a result of osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.
6. Nonunions, correction of functional deformity, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The ICONACY I-Hip system consists of femoral stem and acetabular cup (i.e., shell) porous coated components intended for cementless, press-fit fixation.

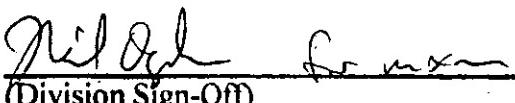
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1

510(k) Number K121034